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FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE (REV. 2-2005)

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

INTERNATIONAL FILING DATE INTERNATIONAL APPLICATION NO. PCT/EP04/004122 April 16, 2004

ATTORNEY'S DOCKET NUMBER

PB60212-2USW

U.S. APPLICATION NO. (If Janowa), see 37 CFR 1.5)

| PRIOR | TY DATE CLAIMED | |
|-------|-----------------|-----|
| | April 17, | 200 |

TITLE OF INVENTION

Combinations of Paroxetine and 4-(S)-(4-Acetyl-Piperazin-1-YL)-2-(R)-(4-Fluoro-2-Methyl-Phenyl)- Piperidine-1-Carboxylic Acid

| | tto, S | T(S) FOR DO/EO/US ergio | | | | |
|-------|-------------|--|--|--|--|--|
| pplic | ant h | erewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | | |
| 1. | \boxtimes | This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. | | | | |
| 2. | | This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. | | | | |
| 3. | | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (9) and (24) indicated below. | | | | |
| 4. | × | The US has been elected (Article 31). | | | | |
| 5. | | A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) | | | | |
| | | a. \square is attached hereto (required only if not communicated by the International Bureau). | | | | |
| | | b. 🗵 has been communicated by the International Bureau. | | | | |
| | | c. \square is not required, as the application was filed in the United States Receiving Office (RO/US). | | | | |
| 6. 🗆 | | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). | | | | |
| | | a. is attached hereto. | | | | |
| | | b. has been previously submitted under 35 U.S.C. 154(d)(4). | | | | |
| 7. | \boxtimes | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) | | | | |
| | | a. are attached hereto (required only if not communicated by the International Bureau). | | | | |
| | | b. have been communicated by the International Bureau. | | | | |
| | | c. \square have not been made; however, the time limit for making such amendments has NOT expired. | | | | |
| | | d. 🛛 have not been made and will not be made. | | | | |
| 8. | | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). | | | | |
| 9. | | An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). | | | | |
| 10. | | An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). | | | | |
| 11. | | A copy of the International Preliminary Examination Report (PCT/IPEA/409). | | | | |
| 12. | \boxtimes | A copy of the International Search Report (PCT/ISA/210). | | | | |
| Ite | ems 1 | 3 to 23 below concern document(s) or information included: | | | | |
| 13. | \boxtimes | An Information Disclosure Statement under 37 CFR 1.97 and 1.98. | | | | |
| 14. | | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. | | | | |
| 15. | \boxtimes | A FIRST preliminary amendment. | | | | |
| 16. | | A SECOND or SUBSEQUENT preliminary amendment. | | | | |
| 17. | | A substitute specification. | | | | |
| 18. | | A power of attorney and/or change of address letter. | | | | |
| 19. | | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. | | | | |
| 20. | | A second copy of the published International Application under 35 U.S.C. 154(d)(4). | | | | |
| 21. | | A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). | | | | |
| 22. | \boxtimes | Express Mail Label No. EV 332063875 US | | | | |
| 23. | \boxtimes | Other items or information: | | | | |
| | | a) PCT Cover Page | | | | |

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Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. U.S. APPIdCATION NOCI (if known, 1596-97) CFR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER PCT/EP04/004122 PB60212-2USW The following fees are submitted: **CALCULATIONS** PTO USE \$300 \$300.00 Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4). \$100 \$200.00 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared and provided to the Office \$400 \$500 \$400.00 TOTAL OF 24, 25 and 26 = \$900.00 Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. **Total Sheets** Extra Sheets Number of each additional 50 or RATE fraction thereof (round up to a whole -100 =/50 = \$250.00 \$ \$0.00 Surcharge of \$130.00 for furnishing the oath or declaration later than months from the \$ earliest claimed priority date (37 CFR 1.492(e)). CLAIMS NUMBER FILED NUMBER EXTRA RATE Total claims 17 - 20 = \$50.00 \$ \$0.00 х Independent claims 2 0 - 3 = \$200.00 \$0.00 MULTIPLE DEPENDENT CLAIMS (if applicable) \$360.00 \$0.00 **TOTAL OF ABOVE CALCULATIONS =** \$900.00 Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are \$0.00 reduced by 1/2. SUBTOTAL = \$900.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from \$ \$0.00 the earliest claimed priority date (37 CFR 1.492(f)). \$900.00 **TOTAL NATIONAL FEE =** Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property \$0.00 TOTAL FEES ENCLOSED = \$900.00 Amount to be \$ Amount to be \$ a. A check in the amount of \$ to cover the above fees is enclosed. b. Please charge my Deposit Account No. 07-1392 \$900.00 in the amount of to cover the above fees. A duplicate copy of this sheet is enclosed. c. X The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1392 . A duplicate copy of this sheet is enclosed. d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status SEND ALL CORRESPONDENCE TO: SIGNATURE Lorie Ann Morgan 23347 NAME 38,181 REGISTRATION NUMBER

| | JC20 Rec'd PCT/PTO 1 2 OCT 2005 | | | | | |
|--------------------------------------|---|--|--|------------------------------|--|--|
| CERTIFICATE O Applicant(s): Melotto | | Docket No. PB60212-2USW | | | | |
| O Application No. 7 1 To Be Assigned | Filing Date Concurrently Herewith | Examiner | Customer No. 23347 | Group Art Unit | | |
| I ibeliulie | tions of Paroxetine and 4-(Se-1-Carboxylic Acid '1-(R)- n and/or Anxiety | S)-(4-Acetyl-Piperazin-1-YL)-2-(R)-(4-J -(3,5-BIS-Trifluoromethyl-Phenyl)-Eth | Fluoro-2-Methyl-I Iyl!Methylamide F | Phenyl)- 'or Treatment of | | |
| I hereby certify that | the following corresponder | :nce: | | | | |
| Transmittal of Natio | onal Phase Application w/ac | | | | | |
| | | dentify type of correspondence) | | | | |
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| | Ctober 12, 2009 (Date) | missioner for Patents, P.O. Box 1450, | , Alexandria, VA 2 | 22313-1450 on | | |
| | | Valerie L. | Phillips | | | |
| | | (Typed or Printed Name of Person Value L. M. (Signature of Person Maili | ellen | ence) | | |
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